IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

SHERRY L. JONES	§	
	§	
v.	§	Case No. 6:07-cv-455
	§	
BLACKSTONE MEDICAL, INC.; SCT, INC.; and DISANTO TECHNOLOGY, INC.	§	

ORDER ON DEFENDANT DISANTO TECHNOLOGY, INC.'S MOTION TO DISMISS

Plaintiff Sherry Jones has filed a products liability suit against Defendants Blackstone Medical, Inc. ("Blackstone"), SCT, Inc. ("SCT"), and DiSanto Technology, Inc. ("DiSanto") to recover for injuries caused by the 3º Anterior Cervical Plating System, an implant. Pending before the Court is Defendant DiSanto's motion to dismiss for failure to state a claim against DiSanto in accordance with the Biomaterials Access Assurance Act, 21 U.S.C. § 1601, *et seq.* (Doc. No. 63). The Court, having reviewed the pleadings, exhibits, and the applicable law, grants in part and denies in part DiSanto's motion to dismiss.

BACKGROUND

In 2002, Jones had the 3º Anterior Cervical Plating System (hereafter "the implant") implanted in her neck. By 2005, Jones began experiencing a choking sensation, pain, problems swallowing, and tension in the area around the surgical site. After testing, she learned that the screws that attached the implant to her C4-5, C5-6, and C6-7 vertebras were fractured. Later when the implant was removed from her neck, Jones learned that the implant's top-locking plate was bent.

Jones filed suit complaining that the implant was defectively designed, marketed, and manufactured. As alleged by Jones, Blackstone designed and manufactured the implant, SCT

manufactured the screws that attached the implant to her vertebras, and DiSanto manufactured the implant's top-locking plate.

As to DiSanto, Jones specifically alleged that DiSanto defectively designed, marketed, and manufactured the top-locking plate. Jones further complained that the top-locking plate was unsafe for its intended purpose and not adequately tested.

In response to the complaint, DiSanto filed a motion to dismiss arguing that because DiSanto was a "biomaterials supplier", as the term is defined by the Biomaterials Access Assurance Act, DiSanto could not be liable for injuries caused by the implant.

STANDARD

Rule 12(b)(6) permits a party to move for dismissal of a claim because of the plaintiff's "failure to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). Under Rule 8(a), a complaint need only contain a "short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a). Generally, when considering motions to dismiss, the court must liberally construe the complaint in favor of the plaintiff, and all facts pleaded in the complaint must be taken as true. *Lowrey v. Tex. A&M Univ. Sys.*, 117 F.3d 242, 247 (5th Cir. 1997) (citing *Campbell v. Wells Fargo Bank*, 781 F.2d 440, 442 (5th Cir. 1986)).

But, in a case involving a biomaterials supplier, the Biomaterials Access Assurance Act ("the Act") provides otherwise. Title 21 U.S.C. § 1605(a) provides that, "[a] defendant may . . . move to dismiss an action against it on the grounds that the defendant is a biomaterials supplier" and the defendant is not liable as a manufacturer (under 21 U.S.C. § 1604(b)), as a seller (under 21 U.S.C. § 1604(c)), or for furnishing raw materials or component parts for an implant that failed to meet applicable contractual requirements or specifications (under 21 U.S.C. § 1604(d)). Therefore, to

prevail on its motion to dismiss under the Act, DiSanto must demonstrate that (1) it is a "biomaterials supplier", (2) the Act applies to Jones' claims, and (3) it is not liable as the "manufacturer" of the implant, is not liable as a "seller" of the implant, and did not provide component parts for the implant that were in derogation of contractual requirements or specifications. *See* 21 U.S.C. § 1605(a).

Pursuant to the Act, the court must rule on the motion to dismiss solely on the basis of the pleadings and any affidavits. *See id.* § 1605(c)(3). Further, the Act allows the court to dismiss biomaterials suppliers prior to discovery. *See id.* § 1605(c)(1)(A). Under this standard, the Court will review DiSanto's motion to dismiss.

ANALYSIS

A. "Biomaterials Supplier" Under the Act

The Act defines a "biomaterials supplier" as "an entity that directly or indirectly supplies component parts or raw materials for use in the manufacture of an implant." *Id.* § 1602(1)(A). Here, DiSanto produced uncontested evidence demonstrating that DiSanto supplied the top-locking plate for Blackstone's implant according to Blackstone's specifications. Further, DiSanto produced uncontested evidence that the top-locking plate is a component part as defined by the Act. Accordingly, the Court finds that DiSanto is a biomaterials supplier.

B. Application of the Act to Component Part Manufacturers

Next, the Court must decide whether the Act applies to Jones' claims against DiSanto. Jones argues that the Act does not apply to her causes of action because the top-locking plate was specifically designed for 3º Anterior Cervical Plating System. Citing to the Congressional findings in § 1601, Jones argues that the Act does not apply to component parts that are manufactured

specifically for use in medical devices.

But Jones' interpretation of the Act runs contrary to the statutory language. Title 21 U.S.C. § 1604(a)(3) provides that, "a biomaterials supplier shall not be liable . . . for furnishing . . . component parts for the implant that failed to meet applicable contractual requirements or specifications". The Court finds that the literal language of subsection 3 envisions the situation where a manufacturer of a medical device contracts with another manufacturer to produce a specific component part that will be incorporated into a medical device.

C. Liable Under the Act

1. Manufacturer

Under the Act, a biomaterials supplier will only be held liable as a manufacturer of an implant if the biomaterials supplier – "(A)(i) registered or was required to register with the Secretary [of Health and Human Services] pursuant to [21 U.S.C.] Section 360 . . . and (ii) included or was required to include the implant on the list of devices filed with the Secretary pursuant to Section 360(j); (B) is the subject of a declaration issued by the Secretary pursuant to paragraph (3) that states that the supplier . . . was required to – (i) register with the Secretary . . . but failed to do so; or (ii) include the implant on a list of devices filed with the Secretary . . . but failed to do so; or (C) is related by common ownership or control to a person meeting all the requirements described above." *Id.* § 1604(b)(2).

Here, DiSanto produced sufficient uncontested evidence demonstrating that DiSanto did not fit any of the above categories. Therefore, pursuant to the Act, the Court finds that to the extent Plaintiff Sherry Jones sought to hold DiSanto liable as a manufacturer of the top-locking plate, Jones' claims are dismissed. *Id.* § 1605 (c)(3).

2. Seller

Under the Act, a biomaterials supplier may be liable as the seller of a component part if the biomaterials supplier – "(A) held title to the implant and then acted as a seller of the implant after its initial sale by the manufacturer; or (B) acted under contract as a seller to arrange for the transfer of the implant directly to the claimant after the initial sale by the manufacturer of the implant; or (2) is related by common ownership or control to a person meeting all the requirements described above." *Id.* § 1604(c).

Here, DiSanto produced sufficient uncontested evidence demonstrating that DiSanto did not fall under any of the above categories. Therefore, pursuant to the Act, the Court finds that to the extent Plaintiff Sherry Jones sought to hold DiSanto liable as a seller of the top-locking plate, Jones' claims are dismissed. *Id.* § 1605(c)(3).

3. Failure to Meet Applicable Contractual Requirements or Specifications

Under the Act, a biomaterials supplier may be liable under the Act if – "(1) the biomaterials supplier supplied raw materials or component parts for use in the implant that either – (A) did not constitute the product described in the contract between the biomaterials supplier and the person who contracted for the supplying of the product; or (B) failed to meet any specifications . . . and (2) such failure to meet applicable contractual requirements or specifications was an actual and proximate cause of the harm to the claimant." *Id.* § 1604(d).

The Court finds that DiSanto produced uncontested evidence demonstrating that DiSanto could not be held liable under § 1604(d) of the Act. However, § 1605(c) provides that the court may, before ruling on a motion to dismiss, permit discovery limited to matters that are directly relevant to the issue of whether the biomaterials supplier failed to meet applicable contractual requirements

and specifications. Pursuant to § 1605(c), the Court is will allow limited discovery on this issue.

CONCLUSION

For the reasons previously stated, it is ORDERED that Plaintiff Sherry Jones' claims to hold DiSanto Technology, Inc. liable as a manufacturer and as the seller of the top-locking plate are dismissed.

It is further that Plaintiff Sherry Jones shall have until February 2, 2009 to conduct limited discovery on the issue of whether Defendant DiSanto Technology, Inc. failed to meet applicable contractual requirements and specifications. Defendant DiSanto Technology, Inc. shall have until February 9, 2009 to file an amended motion to dismiss on that issue.

Further, the Court DENIES Defendant DiSanto Technology, Inc.'s Agreed Motion to Extend Deadline (Doc. No. 73) as MOOT.

It is SO ORDERED.

SIGNED this 10th day of November, 2008.

MICHAEL H. SCHNEIDER
UNITED STATES DISTRICT JUDGE